 K112475

NOV 10 2011

4.0 510(k) Summary (Prepared August 20, 2011):

In accordance with 21 CFR Section 807.92, Xtract Solutions. Is submitting the following 510(k) Summary:

4.1 Submitter Information –

Xtract Solutions
9495 SW Locust, Suite E
Portland, OR 97223, USA
FDA Registration No.: 3008292087
Owner / Operator No.: EIN 931264310

4.2 Preparer of Submission and Contact for Information –

Keith Lowrey, Vice President of Regulatory Affairs & Quality Assurance
Xtract Solutions
9495 SW Locust Street, Suite E
Portland, OR 97223
Date of Preparation: ***August 20, 2011***

Contact Information for 510(k) Correspondence:

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Grants Pass, OR 97526
Office: 541-476-1628
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E-mail: Lowrey_RA_QA_Soutions@yahoo.com

4.3 Name of Device –

4.3.1 Trade / Proprietary Name:
Xtract 3mL Syringe Keys

4.3.2 Common / Usual Name:
Hypodermic Syringe Accessory Spacer or Holder

4.3.3 Classification Name:
Accessory Device to Piston Hypodermic Syringe

4.4.4 Regulation Number:
21 CFR 880.5860

4.4.5 Product Code:
The product code for the Syringe Keys is **FMF**.

4.4.6 Class:
Class II (performance standards)

4.4 Substantial Equivalence –

This submission establishes the substantial equivalence of the *Xtract Solutions 3mL Syringe Keys* as an accessory to piston hypodermic syringes such as the following predicate device:

4.4.1 Xtract Solutions Syringe Keys, **K091200**, SE 08/21/2009, manufactured by Xtract Solutions, Portland, OR.

4.4.2 Xtract Solutions has added to the "family of Xtract Solutions Syringe Keys" four (4) additional Syringe Keys to accommodate 3 mL piston hypodermic syringes.

4.5 Description of the Device –

4.5.1 The Xtract Solutions 3 mL Syringe Key is a hand held passive tool and an accessory designed to conveniently and ergonomically fit between the plunger thumb rest and the finger grip of piston hypodermic syringes.

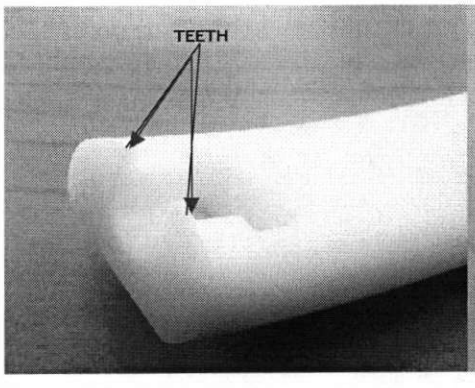

Figure 1 Teeth hold the finger grip of syringe.

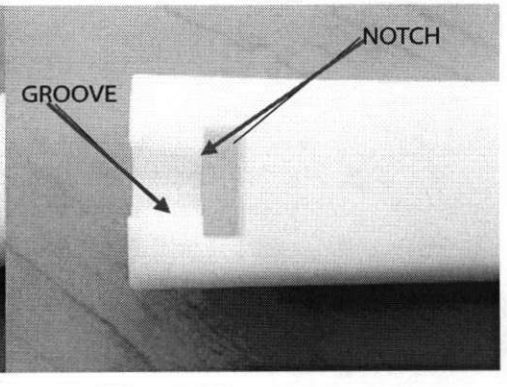

Figure 2 The notch holds the end of the plunger.

4.5.2 The 3 mL Syringe Key facilitates the user in obtaining rapid and accurate volumetric with-drawls from vials containing vaccines and other medications. The Syringe Key has been re-designed for ergonomic improvement for the user and to fit four (4) additional piston hypodermic syringes:

- 3 mL VanishPoint (RTI10311) syringes, 23g x 1"
- 3 mL BD SafetyGlide (BD305905) syringes, 23g x 1"
- 3 mL BD Integra (BD305271) syringes 23g x 1"
- 3 mL BD Precision Glide (BD309578) syringes 20g x 1"

4.5.3 The 3 mL Syringe Key is 5 inches long and is curved to fit comfortably in the user's hand.

4.5.4

Figure 3 Key is curved to provide ergonomic grip by user

4.5.5 At the top of the Key on the underside are three features:

Teeth: These raised points allow the user to pull out the syringe plunger easily.

Groove: The width of the groove corresponds to the type of syringe designated for the specific Key. *The length of the groove equates to the dose the Key will withdraw.

Notch: The notch holds the end of the plunger secure when pulling back and pushing forward to measure the dose.

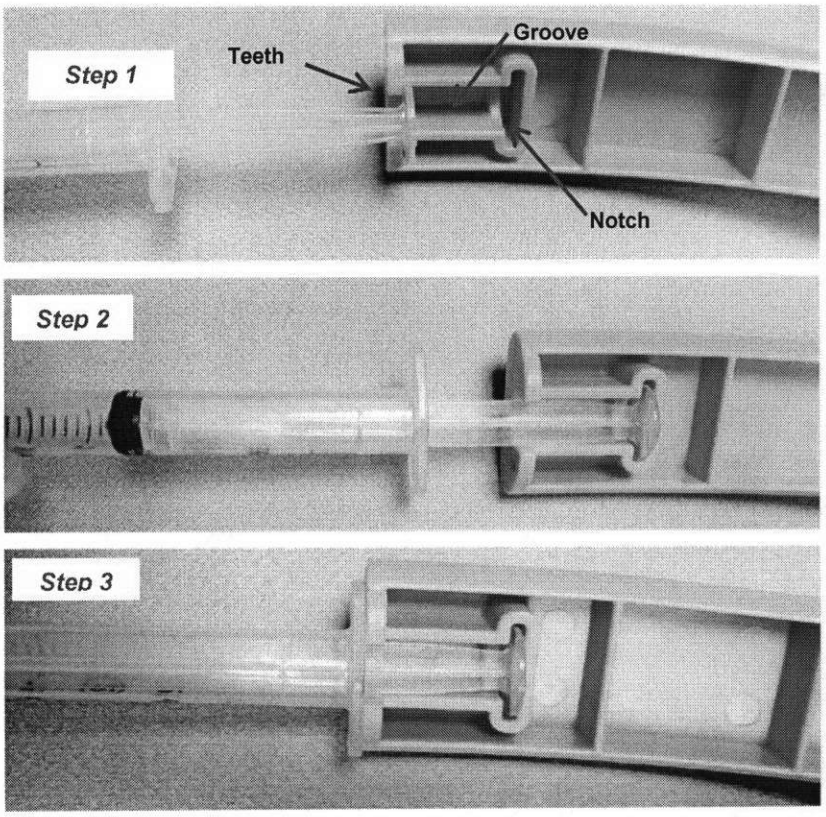

Figure 4 Key controls the distance the syringe plunger can be drawn through the syringe barrel

4.5.5 The plunger is pulled slightly from the syringe barrel (***Step 1***) and the plunger thumb rest is then nested into a precise slot located at the proximal end of the Syringe Key (***Step 2***). After seating the thumb rest in the Syringe Key, the syringe's barrel is moved backward against the proximal flat face of the Syringe Key (***Step 3***).

4.6 Indications for Use –

4.6.1 The product family of Xtract Solutions Syringe Keys are indicated as accessories provided for specified commercially available piston hypodermic syringes (for medical purposes) which are designed to control the distance the syringe plunger can be drawn through the syringe barrel and to facilitate the user in obtaining accurate, consistent and precise volumetric draws from vials containing liquids such as vaccinations, allergenic extracts and other medications. The Syringe Keys (available for 1mL and/or 3 mL hypodermic syringes) are designed as an accessory only for the following syringes:

4.6.1.1 ***1 mL syringes:***

- 1 mL Terumo SurSaver Mixing Syringes (SS01A2313T) and/or
- 1 mL Greer Optimix (GROM-23) SurSaver Mixing Syringes.

4.6.1.2 ***3 mL syringes:***

- 3 mL VanishPoint (RTI10311) Syringes, 23g x 1"
- 3 mL BD SafetyGlide (BD305905) Syringes, 23g x 1"
- 3 mL BD Integra (BD305271) Syringes 23g x 1"
- 3 mL BD Precision Glide (BD309578) Syringes 20g x 1"

4.6.2 The device assists the user in withdrawing precise and accurate liquid volume withdraws from a vial. The Syringe Keys do not facilitate or assist the user with injecting the contents of the hypodermic syringe.

4.6.3 The Syringe Keys can be used by medical personnel as well as individuals who are not medical professionals; but, have been instructed in their use.

4.6.4 Syringe Keys are available for specified piston hypodermic syringe models manufactured by designated syringe manufacturers.

4.7 Specifications –

4.7.1 The 3mL Syringe Keys are designed and fabricated for use with the following specified piston hypodermic syringes and specified volume withdrawals:

- mL VanishPoint (RTI10311) Syringes, 23g x 1"
- 3 mL BD SafetyGlide (BD305905) Syringes, 23g x 1"
- 3 mL BD Integra (BD305271) Syringes 23g x 1
- 3 mL BD Precision Glide (BD309578) Syringes 20g x 1"

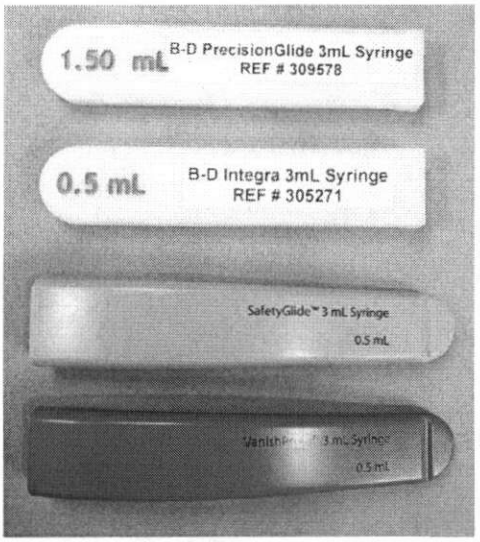

Figure 5 Examples of 3 mL Syringe Keys

4.7.2 The new 3mL Syringe Keys are designed for the following volume withdrawals:

Safety Glide P/N 120-0003	Vanish Point P/N 120-0002	BD Precision Glide P/N 190-0101	BD Integra P/N 190-0110
0.5 mL	0.5 mL	0.5 mL	0.5 mL

4.7.4 The Xtract Solutions 3mL Syringe Keys will be sold by prescription only and labeling will bear the statement, "***Caution: Federal Law restricts this device to sale by or on the order of a physician.***"

4.8 Technological Characteristics in Comparison to the Predicates –

4.8.1 Predicate Device –

The Xtract Solutions 3mL Syringe Key is substantially equivalent to the Xtract Solutions 1mL Syringe Keys, K091200, SE 08/21/2009

Manufacturer: Xtract Solutions, Portland, OR 97223

4.8.2 Materials –

Materials used to fabricate the Xtract 3mL Syringe Keys are polycarbonate/ABS blend and/or Delrin® that have a long use in medical devices.

4.8.3 Performance Comparison–

As an ***accessory*** for the hypodermic syringe, the 3mL Syringe Keys and the 1 mL Syringe Keys are **designed to control** the distance that the syringe plunger can be pulled through the syringe barrel by functioning as a "spacer" fitting on the plunger between the thumb rest and the barrel's finger rest/flange. The devices assist the user in withdrawing precise and accurate liquid volume withdraws from a vial. The devices do not facilitate or assist the user with injecting the contents of the hypodermic syringe.

4.9 Performance Testing –

4.9.1 The 3mL Syringe Keys were designed by first establishing an empirical (not just mathematic) relationship of plunger travel to dispensed volume (weight). This data was then used to establish the ideal physical size of the syringe keys (the "Syringe Key Design" worksheet). This process was used with each of the volume sizes for each 3 mL Syringe Key.

4.9.2 Upon receipt of the 3mL Syringe Keys, a First Article Inspection was performed to verify that all dimensions met drawing specifications and requirements as noted in following graph:

Example data: 3 mL Syringe Keys tested with BD 3 mL Integra Syringes:

Dose Verification at Design Length (0.573")			
Syringe		# 1	#2
DRAW	1	0.502	0.504
	2	0.503	0.506
	3	0.495	0.501
	4	0.499	0.499
	5	0.500	0.506
	6	0.505	0.502
	7	0.500	0.502
	8	0.493	0.500
	9	0.504	0.499
	10	0.503	0.501
	AVG	**0.500**	**0.502**
	STD	0.003893	0.002582

The channel length measurements of the actual syringe keys and the "draw volumes" were evaluated and compared. Using the 3mL Syringe Keys, piston hypodermic syringes with needles were introduced into the septum of vials containing H_20.

The liquid was withdrawn from the vials and dispensed into tarred weighing dishes and subsequently weighed. Weight measurement analyses were conducted on each of the different 3 mL Syringe Keys multiple times.

4.9.3 Performance data demonstrated that the 3mL Syringe Keys facilitate the user in obtaining more accurate, precise and reproducible volume draws as compared to the standard method or visualization procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 10 2011

Xtract Solutions
C/O Keith Lowrey
Vice President of Regulatory Affairs & Quality Assurance
9495 SW Locust Street, Suite E
Portland, Oregon 97223

Re: K112475
Trade/Device Name: Xtract Syringe Keys
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 26, 2011
Received: September 8, 2011

Dear Mr. Lowrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): To be determined by FDA. K112475

Device Name: Xtract Syringe Keys

Indications for Use:

1.1 The product family of Xtract Solutions Syringe Keys are indicated as accessories provided for specified commercially available piston hypodermic syringes (for medical purposes) which are designed to control the distance the syringe plunger can be drawn through the syringe barrel and to facilitate the user in obtaining accurate, consistent and precise volumetric draws from vials containing liquids such as vaccinations, allergenic extracts and other medications. The Syringe Keys (available for 1mL and/or 3 mL hypodermic syringes) are designed as an accessory only for the following syringes:

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1.3 The Syringe Keys can be used by medical personnel as well as individuals who are not medical professionals; but, have been instructed in their use.

1.4 Syringe Keys will be available for specified piston hypodermic syringe models manufactured by designated syringe manufacturers.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112475

Katherine Hufford for Richard C. Chapman
11/10/11